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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SULLIVAN, DANIEL M	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 05/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,026	BERINSTEIN ET AL.	
	Examiner	Art Unit	
	Daniel M. Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-63 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-63, as originally filed, are pending.

Sequence Compliance

The instant application is not fully compliant with the requirements for applications containing nucleotide and/or amino acid sequence disclosures. Specifically, the specification and claims contain sequence that is not identified by SEQ ID NO (e.g., the drawings set forth sequence that is not identified by SEQ ID NO and the claims make reference to sequence disclosed in the drawings.

> "Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application" 37 C.F.R. 1.821(d).

A response to this communication must include amending the specification and claims to refer to each sequence set forth in the disclosure and referenced in the claims by SEQ ID NO.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-30, 40-51 and 58-62, drawn to an expression vector comprising the nucleic acid sequence set forth as SEQ ID NO: 5 or encoding the amino acid sequence set forth as SEQ ID NO: 6, classified in class 435, subclass 320.1.

II. Claims 31-35 and 52-57, drawn to a method of preventing or treating cancer comprising administering an expression vector of Group I, classified in class 514, subclass 44.

III. Claims 36 and 38, drawn to an isolated polypeptide, classified in class 530, subclass 350.

IV. Claims 37 and 39, drawn to a method for immunizing a host against the tumor antigen B5 comprising administering a peptide, classified in class 424, subclass 184.1.

V. Claim 63, drawn to an antibody having the ability to bind to the amino acid sequence of SEQ ID NO: 6, classified in class 424, subclass 130.1.

In addition, the inventions of Group I (claims 40-51) and Group II (claims 52-57) are **further restricted** to the expression vector and method of using the expression vector wherein the at least one additional tumor-associated antigen is a single embodiment selected from the group set forth in claim 40. An election to prosecute the subject matter of Group I or II must also include an election of a single additional tumor-associated antigen for initial prosecution.

Claim 6 link(s) the inventions defined by the distinct tumor associated antigens. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 6. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the

limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Groups III and IV are **further restricted** to prosecution of a single isolated polypeptide. The claims of Groups III and IV are directed to a polypeptide shown in Table X or XI. As the application does not contain a Table X or XI it is impossible to determine the properties of the polypeptides claimed. For the purposes of this restriction requirement, it is presumed that each polypeptide is structurally and functionally distinct (*i.e.*, represents a distinct epitope) and is therefore considered a patentably distinct invention (see *Infra*).

The inventions are distinct, each from the other because of the following reasons:

It appears that the vector of Invention I is related to the proteins of Invention III in that the proteins appear to be fragments of the polypeptide encoded by a nucleic acid comprised in the vector. However, even if that is true, the vector and polypeptides are distinct inventions

because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay. Likewise, the distinct tumor-associated antigens of claims 40-57 are structurally and functionally distinct chemical entities and therefore, absent an allowable generic claim, define distinct inventions.

Searching the polypeptide of Group III with the polynucleotide of Group I would impose a serious burden because the subject matter embraced by the groups is not coextensive. First, the Inventions of Groups I and III are separately classified, which is *prima facie* evidence of the additional burden imposed by searching both inventions together. Furthermore, a search of the nucleic acid and polypeptide sequences must be performed in separate databases and a determination that the nucleic acid of Group I is patentable cannot be taken as evidence for the patentability of the polypeptide of Group III, and *vice versa*. A search for the polypeptide of Group III would not reasonably embrace the subject matter of Group I because the art might disclose the polypeptide without disclosing a nucleic acid sequence encoding the polypeptide. Likewise, a search of the art for the polynucleotide of Group I would not reasonably embrace the full scope of the subject matter of Group III because the art might disclose the polypeptide sequence determined by direct amino acid sequencing, without a disclosure of the nucleic acid sequence. Therefore, a determination that either Group is free of the art does not adequately support patentability of the other Group and an additional search is required to establish patentability.

Although claim 6 is generic to claims directed to the various recited additional tumor-associated antigens and, in the event that the generic claim is deemed allowable search and examination of the linked inventions does not constitute an undue burden on the Office, no such determination has been made in the instant case. In the event that the generic claim is not patentable, a determination of whether each linked invention is patentable over the art is based upon the particulars of the individual linked invention. Therefore, until the generic claim is deemed allowable, search and examination of all linked inventions with the generic invention imposes an undue burden on the Office. As discussed in detail below, if the generic claim is deemed allowable, the linked inventions will be rejoined and examined together with the generic claim.

The polypeptides of Invention III appear to be related to the antibodies of Invention V by virtue of binding affinity. Although the polypeptides and antibodies might be related since the antibody binds to the polypeptide and can be raised by immunization with the polypeptide, they are distinct inventions because they are physically and functionally distinct chemical entities, and the antibody can be obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the polypeptide may be used for processes other than the production of the antibody, such as a standard in an assay for the presence of the protein.

The vector of Invention I is related to the antibodies of Invention V by virtue of the antibodies' binding affinity for a protein encoded by the nucleic acid. Although the nucleic acids and antibodies are related via the polypeptide encoded by the nucleic acids, which binds to the antibodies and can be used to make the antibodies by immunization, they are distinct inventions

because they are physically and functionally distinct chemical entities, and the antibody can be made obtained by another and materially different process, such as by purification from a natural source or by immunization with chemically synthesized peptides. Further, the nucleic acid may be used for processes other than the production of the protein, such as a nucleic acid hybridization assay.

Searching the antibody of Group V with the polypeptide of Group III or nucleic acid of Group I would impose a serious burden on the office. Again, the Inventions are separately classified, which is *prima facie* evidence of the additional burden imposed by searching the inventions together. Furthermore, a determination that the antibody of Group V is free of the art does not adequately support patentability of the claimed protein or nucleic acids and *vice versa*. Because the art might disclose the protein or nucleic acid independently of an antibody that binds to the polypeptide or polypeptide encoded by the nucleic acid, and because an antibody that binds to the polypeptide of Invention III or encoded by the nucleic acid of Invention I might be disclosed in the absence of a disclosed polypeptide or nucleic acid sequence, determining patentability of Group V requires additional searching beyond what is required for Group I or Group III, and determining patentability of Group I and Group III requires searching beyond a search for the subject matter of Group V.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different

process, such as an *in vitro* method of expressing the encoded polypeptide or as a nucleic acid probe.

Inventions III and IV are also related as product and process of use. The inventions are distinct, however, because the product as claimed can be used in a materially different process. For example, the peptides could be used as standards in an *in vitro* assay for the protein.

Although the Office acknowledges that in the event a product claim is deemed allowable, determining patentability of process claims that depend from or otherwise include all the limitations of the allowable product claim does not impose an undue burden (see below), no such determination of patentability has been made in the instant case. In the event that the product is not patentable, a determination of whether each method of making and using the product is patentable over the art is based upon the particulars of the method and not on the product made by or used in the method. Conversely, a search of any given process of making or using the product does not adequately support patentability of the product because the product can be made by or used in a materially different process. Therefore, until the product is deemed allowable, search and examination of the process claims with the product imposes an undue burden on the Office. As discussed in detail below, if a product claim is found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04.

Inventions II and IV are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See

MPEP § 806.05(j). In the instant case, the method of Group II comprises preventing or treating cancer by administering a nucleic acid vector and the method of Group IV is directed to a method of immunizing a host against a B5 antigen by administering a peptide. Each method clearly has a materially different design and mode of operation as the methods comprise the administration of chemically and functionally distinct biological molecules to provide materially different outcomes.

In the absence of an allowable product claim to which the process claims are limited to making or using, examining the distinct methods together in a single application would impose a serious burden on the Office. *Prima facie* evidence for the additional burden imposed by examining each additional method is again evidenced by the separate classification of each method. Furthermore, as each method is limited to comprising elements to which the other methods are not limited, examination of each method requires a separate search for those elements that distinguish the respective methods. In addition, because each method encompasses subject matter not encompassed by the other method, a determination that any one method is patentable over the art does not adequately support patentability of any of the other method. Therefore, patentability of each method must be determined separately.

The product of inventions III and V are unrelated to the method of Invention II and the products of Inventions I and V are unrelated to the method of invention IV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the products are neither made by nor used in the respective methods.

As the products and processes are unrelated and therefore might be disclosed independently of one another, a search and examination of the unrelated inventions together in a single application would constitute an undue burden on the Office.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Rejoinder in view of *In re Ochiai, In re Brouwer*

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process

claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP, § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Friday 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

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